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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,658	05/18/2005	Amanda Proudfoot	ARS-104	9141
23557 7590 03/29/2007 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			EXAMINER MERTZ, PREMA MARIA	
			ART UNIT 1646	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
31 DAYS		03/29/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/510,658	Applicant(s) PROUDFOOT ET AL.	
	Examiner Prema M. Mertz	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 22-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restriction

1. This application is a 371 of PCT/EP03/50097. For applications filed under 371, PCT rules for lack of unity apply.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains inventions or groups of inventions, which are not so linked as to form a single inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Groups 1-15. Claims 22-26, 31, drawn to a human MCP-1 antagonist selected from a mutant of MCP-1 with mutations:

- (a) at amino acids 18 and 19;
- (b) at amino acids 18 and 58;
- (c) at amino acids 19 and 58;
- (d) at amino acids 18, 19 and 58;
- (e) at amino acids 18 and 66;
- (f) at amino acids 19 and 56;
- (g) at amino acids 18, 19 and 66;
- (h) at amino acids 18, 58 and 66;
- (i) at amino acids 19, 58 and 66;
- (j) at amino acids 18, 19, 58 and 66;
- (k) at amino acid 18 with one or more of the following: 24, 44, 49, 75;

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- (l) at amino acid 19 with one or more of the following: 24, 44, 49, 75; and
- (m) at amino acids 18, 19 and one or more of the following: 24, 44, 49, 75.

Groups 16-30. Claims 27-30, drawn to a nucleic acid encoding a human MCP-1 antagonist, an expression vector, a host cell and a process of preparing the MCP antagonist, wherein the antagonist is selected from a mutant of MCP-1 with mutations:

- (a) at amino acids 18 and 19;
- (b) at amino acids 18 and 58;
- (c) at amino acids 19 and 58;
- (d) at amino acids 18, 19 and 58;
- (e) at amino acids 18 and 66;
- (f) at amino acids 19 and 56;
- (g) at amino acids 18, 19 and 66;
- (h) at amino acids 18, 58 and 66;
- (i) at amino acids 19, 58 and 66;
- (j) at amino acids 18, 19, 58 and 66;
- (k) at amino acid 18 with one or more of the following: 24, 44, 49, 75;
- (l) at amino acid 19 with one or more of the following: 24, 44, 49, 75; and
- (m) at amino acids 18, 19 and one or more of the following: 24, 44, 49, 75.

Groups 31-45. Claim 31, drawn to a method of reducing leukocyte migration and activation *in vitro* by contacting leukocytes with a human MCP-1 antagonist selected from a mutant of MCP-1 with mutations:

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- (a) at amino acids 18 and 19;
- (b) at amino acids 18 and 58;
- © at amino acids 19 and 58;
- (d) at amino acids 18, 19 and 58;
- (e) at amino acids 18 and 66;
- (f) at amino acids 19 and 56;
- (g) at amino acids 18, 19 and 66;
- (h) at amino acids 18, 58 and 66;
- (i) at amino acids 19, 58 and 66;
- (j) at amino acids 18, 19, 58 and 66;
- (k) at amino acid 18 with one or more of the following: 24, 44, 49, 75;
- (l) at amino acid 19 with one or more of the following: 24, 44, 49, 75; and
- (m) at amino acids 18, 19 and one or more of the following: 24, 44, 49, 75.

Groups 46-60. Claims 33-34, drawn to a method of treating a vascular disorder by administering a human MCP-1 antagonist selected from a mutant of MCP-1 with mutations:

- (a) at amino acids 18 and 19;
- (b) at amino acids 18 and 58;
- © at amino acids 19 and 58;
- (d) at amino acids 18, 19 and 58;
- (e) at amino acids 18 and 66;
- (f) at amino acids 19 and 56;

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- (g) at amino acids 18, 19 and 66;
- (h) at amino acids 18, 58 and 66;
- (i) at amino acids 19, 58 and 66;
- (j) at amino acids 18, 19, 58 and 66;
- (k) at amino acid 18 with one or more of the following: 24, 44, 49, 75;
- (l) at amino acid 19 with one or more of the following: 24, 44, 49, 75; and
- (m) at amino acids 18, 19 and one or more of the following: 24, 44, 49, 75.

Groups 61-75. Claims 33-34, drawn to a method of treating cancer by administering a human MCP-1 antagonist selected from a mutant of MCP-1 with mutations:

- (a) at amino acids 18 and 19;
- (b) at amino acids 18 and 58;
- (c) at amino acids 19 and 58;
- (d) at amino acids 18, 19 and 58;
- (e) at amino acids 18 and 66;
- (f) at amino acids 19 and 56;
- (g) at amino acids 18, 19 and 66;
- (h) at amino acids 18, 58 and 66;
- (i) at amino acids 19, 58 and 66;
- (j) at amino acids 18, 19, 58 and 66;
- (k) at amino acid 18 with one or more of the following: 24, 44, 49, 75;
- (l) at amino acid 19 with one or more of the following: 24, 44, 49, 75; and
- (m) at amino acids 18, 19 and one or more of the following: 24, 44, 49, 75.

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Groups 76-90. Claims 33-34, drawn to a method of treating inflammatory diseases by administering a human MCP-1 antagonist selected from a mutant of MCP-1 with mutations:

- (a) at amino acids 18 and 19;
- (b) at amino acids 18 and 58;
- (c) at amino acids 19 and 58;
- (d) at amino acids 18, 19 and 58;
- (e) at amino acids 18 and 66;
- (f) at amino acids 19 and 56;
- (g) at amino acids 18, 19 and 66;
- (h) at amino acids 18, 58 and 66;
- (i) at amino acids 19, 58 and 66;
- (j) at amino acids 18, 19, 58 and 66;
- (k) at amino acid 18 with one or more of the following: 24, 44, 49, 75;
- (l) at amino acid 19 with one or more of the following: 24, 44, 49, 75; and
- (m) at amino acids 18, 19 and one or more of the following: 24, 44, 49, 75.

Groups 91-105. Claims 33-34, drawn to a method of treating autoimmune diseases by administering a human MCP-1 antagonist selected from a mutant of MCP-1 with mutations:

- (a) at amino acids 18 and 19;
- (b) at amino acids 18 and 58;

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- © at amino acids 19 and 58;
- (d) at amino acids 18, 19 and 58;
- (e) at amino acids 18 and 66;
- (f) at amino acids 19 and 56;
- (g) at amino acids 18, 19 and 66;
- (h) at amino acids 18, 58 and 66;
- (i) at amino acids 19, 58 and 66;
- (j) at amino acids 18, 19, 58 and 66;
- (k) at amino acid 18 with one or more of the following: 24, 44, 49, 75;
- (l) at amino acid 19 with one or more of the following: 24, 44, 49, 75; and
- (m) at amino acids 18, 19 and one or more of the following: 24, 44, 49, 75.

Groups 106-120. Claims 33-34, drawn to a method of treating infections by administering a human MCP-1 antagonist selected from a mutant of MCP-1 with mutations:

- (a) at amino acids 18 and 19;
- (b) at amino acids 18 and 58;
- © at amino acids 19 and 58;
- (d) at amino acids 18, 19 and 58;
- (e) at amino acids 18 and 66;
- (f) at amino acids 19 and 56;
- (g) at amino acids 18, 19 and 66;
- (h) at amino acids 18, 58 and 66;

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- (i) at amino acids 19, 58 and 66;
- (j) at amino acids 18, 19, 58 and 66;
- (k) at amino acid 18 with one or more of the following: 24, 44, 49, 75;
- (l) at amino acid 19 with one or more of the following: 24, 44, 49, 75; and
- (m) at amino acids 18, 19 and one or more of the following: 24, 44, 49, 75.

NOTE: Independent claims 22 and 27 encompass thousands of MCP-1 peptide sequences that are not related in structure, and therefore these claims are considered to comprise improper Markush groups. These claims are not proper linking claims because they, in fact, comprise multitudes of sequences.

Applicants must choose a single MCP-1 peptide for examination. This is not a species election, but an election of a single invention.

The inventions listed as Groups I-72 do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2 they lack the same or corresponding special technical feature for the following reasons:

The PCT rules define a special technical feature as a feature, which defines a contribution over the prior art. The first claimed invention fails to recite such a feature, since Hemmerich et al (1999) discloses antagonist of MCP-1 comprising a MCP-1 mutant in which the amino acids at 19 and 58 are substituted (Figure 3, page 13017). Since the first claimed invention lacks a special technical feature, the other claimed inventions cannot share a special technical feature with the first claimed invention.

The inventions of Groups 1-15 are patentably distinct from the products of Groups 16-30 because the products of Groups 1-15 can be synthesized by a materially different method, such as by chemical synthesis. The inventions of Groups 16-30 are

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patentably distinct from the products of Groups 1-15 because the products of Groups 1-15 can be used in methods that are materially different from the methods in which the inventions of Groups 1-15 are used, such as in gene therapy. The methods of Groups 15-45, 46-60, 61-75, 76-90, 91-105, 106-120, are patentably distinct from each other because each method uses different patient populations, different starting materials and has different goals and the search of all methods in one patent application would result in an undue search burden.

2. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Rejoinder under In re Ochiai and In re Brouwer

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP §

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821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

Prema Mertz Ph.D., J.D.
Primary Examiner
Art Unit 1646
March 21, 2007